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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2012-0026]

Pioneer Hi-Bred International, Inc.; Availability of Petition, Plant Pest Risk Assessment, and Environmental Assessment for Determination of Nonregulated Status of Maize Genetically Engineered for Herbicide Tolerance and Insect Resistance

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service has received a petition from Pioneer Hi-Bred International, Inc., (Pioneer) seeking a determination of nonregulated status of maize designated as maize event DP-ØØ4114-3, which has been genetically engineered to be resistant to certain lepidopteran and coleopteran pests and tolerant to the herbicide glufosinate. The petition has been submitted in accordance with our regulations concerning the introduction of certain genetically engineered organisms and products. We are soliciting comments on whether this genetically engineered maize is likely to pose a plant pest risk. We are making available for public comment the Pioneer petition, our plant pest risk assessment, and our draft environmental assessment for the proposed determination of nonregulated status.

DATES: We will consider all comments that we receive on or before [Insert date 60 days after date of publication in the Federal Register].

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to
<http://www.regulations.gov/#!documentDetail;D=APHIS-2012-0026-0001>.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2012-0026, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0026> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

The petition, draft environmental assessment, and plant pest risk assessment are also available on the APHIS Web site at http://www.aphis.usda.gov/brs/aphisdocs/11_24401p.pdf, http://www.aphis.usda.gov/brs/aphisdocs/11_24401p_dea.pdf, and http://www.aphis.usda.gov/brs/aphisdocs/11_24401p_dpra.pdf.

FOR FURTHER INFORMATION CONTACT: Dr. John Turner, Director, Environmental Risk Analysis Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 851-3954, email: john.t.turner@aphis.usda.gov. To obtain copies of the petition, draft environmental assessment, or plant pest risk assessment, contact Ms. Cindy Eck at (301) 851-3892, email: cynthia.a.eck@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

Under the authority of the plant pest provisions of the Plant Protection Act (7 U.S.C. 7701 et seq.), the regulations in 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests," regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered organisms and products are considered "regulated articles."

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. Paragraphs (b) and (c) of § 340.6 describe the form that a petition for a determination of nonregulated status must take and the information that must be included in the petition.

APHIS has received a petition (APHIS Petition Number 11-244-01p) from Pioneer Hi-Bred International, Inc., (Pioneer) of Johnston, IA, seeking a determination of nonregulated status of maize (Zea mays) designated as maize event DP-ØØ4114-3 (event 4114). Event 4114 has been genetically engineered to be resistant to certain lepidopteran pests, including European corn borer (Ostrinia nubilalis), and certain coleopteran pests, including western corn rootworm (Diabrotica virgifera virgifera), and tolerant to the herbicide glufosinate. The petition states that this maize is unlikely to pose a plant pest risk and, therefore, should not be a regulated article under APHIS' regulations in 7 CFR part 340.

As described in the petition, event 4114 has been genetically engineered to produce the Cry proteins Cry1F, Cry34Ab1, and Cry35Ab1, as well as the herbicide tolerance protein phosphinothricin acetyltransferase (PAT). The Cry1F protein confers resistance to certain lepidopteran pests, including European corn borer; the Cry34Ab1 and Cry35Ab1 proteins confers resistance to certain coleopteran pests, including the western corn rootworm; and the PAT protein confers tolerance to the herbicidal active ingredient glufosinate-ammonium at current labeled rates. Event 4114 is currently regulated under 7 CFR part 340. Interstate movements and field tests of event 4114 have been conducted under permits issued or notifications acknowledged by APHIS.

Field tests conducted under APHIS oversight allowed for evaluation in a natural agricultural setting while imposing measures to minimize the risk of persistence in the environment after completion of the test. Data are gathered on multiple parameters and used by the applicant to evaluate agronomic characteristics and product performance. These and other data are used by APHIS to determine if the new variety poses a plant pest risk.

In section 403 of the Plant Protection Act, "plant pest" is defined as any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product: A protozoan, a nonhuman animal, a parasitic plant, a bacterium, a fungus, a virus or viroid, an infectious agent or other pathogen, or any article similar to or allied with any of the foregoing. APHIS has prepared a plant pest risk assessment to determine if event 4114 is unlikely to pose a plant pest risk.

APHIS has also prepared a draft environmental assessment (EA) in which it presents two alternatives based on its analyses of data submitted by Pioneer, a review of other scientific data, and field tests conducted under APHIS oversight. APHIS is considering the following

alternatives: (1) Take no action, i.e., APHIS would not change the regulatory status of maize event 4114 and it would continue to be a regulated article, or (2) make a determination of nonregulated status of event 4114.

The draft EA has been prepared to provide the APHIS decisionmaker with a review and analysis of any potential environmental impacts associated with the proposed determination of nonregulated status of event 4114. The draft EA was prepared in accordance with (1) the National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 et seq.), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Paragraph (d) of § 340.6 provides that APHIS will publish a notice in the Federal Register providing 60 days for public comment for petitions for a determination of nonregulated status. In accordance with § 340.6(d) of the regulations, we are publishing this notice to inform the public that APHIS will accept written comments regarding the petition for a determination of nonregulated status from interested or affected persons for a period of 60 days from the date of this notice. We are also soliciting written comments from interested or affected persons on the plant pest risk assessment and the draft EA prepared to examine any potential environmental impacts of the proposed determination of nonregulated status of the subject maize line. The petition, draft EA, and plant pest risk assessment are available for public review, and copies of the petition, draft EA, and plant pest risk assessment are available as indicated under ADDRESSES and FOR FURTHER INFORMATION CONTACT above.

After the comment period closes, APHIS will review all written comments received during the comment period and any other relevant information. All comments received

regarding the petition, draft EA, and plant pest risk assessment will be available for public review. After reviewing and evaluating the comments on the petition, the draft EA, plant pest risk assessment, and other data, APHIS will furnish a response to the petitioner, either approving or denying the petition. APHIS will also publish a notice in the Federal Register announcing the regulatory status of event 4114 and the availability of APHIS' written environmental decision and regulatory determination.

Authority: 7 U.S.C. 7701-7772 and 7781-7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 22nd day of February 2013.

Michael Gregoire

Deputy Administrator, Biotechnology Regulatory Services, Animal and Plant Health Inspection Service.

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